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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,502

02/22/2002

Jeffrey L. Cleland

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25226 7590 12/09/2009  
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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/080,502	<b>Applicant(s)</b> CLELAND ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-11,14-16,19-22,44,48,56-58,60-64,66-73 and 75-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5,6,9-11, 14, 16, 19, 20-22, 44, 48, 56-58, 60- 63, 66-73, 75-81, 84-88 is/are rejected.
- 7) ☒ Claim(s) 4,15, 55, 64, 65, 82 and 83 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the request for continued examination filed 09/23/2009.

The following rejection is maintained in this action:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5,6,9-11, 14, 16, 19, 20-22, 44, 48, 55-58, 60- 63, 66-73, 75-81, 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/US97/23659 (Brodeck et al).

Brodeck et al disclose a viscous gel vehicle comprising a biocompatible polymer, a mixture of solvents and a bioactive (see Abstract; page 13, lines 1-6). The mixture itself may comprise hydrophobic and hydrophilic solvents in admixture so as to form a solvent with a water solubility of less than 1 wt % (see page 24, lines 20-210). The viscosity of the gel may be less than 1000 centipoise ( see page 3, line 6). The solvent mixture is more specifically defined as a mixture of hydrophilic solvent (Which can be up to 50 wt % and a hydrophobic solvent. Benzyl benzoate is specifically recited as the hydrophobic

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solvent and can be found at concentrations of greater than 50% or 80 % (see page 28, lines 1-23). The beneficial agent can be found at a concentration of between 1 and 50% at page 4, lines 7-8. The concentration of the beneficial agent can be up to 100 mg/ml. (see page 51, lines 12 and 14). Release of the bioactive within the first 24 hrs is 20% or less (see page 2, lines 17-21). The bioactive may be dispersed or dissolved in the gel as shown at page 11, line 8 , as well as throughout the specification. Viscosity of the gel is found at page 37, line 6. The particular combination of solvents, polymers and bioactives may be found at page 28, lines 1-2; page 23, lines 3-24; page 24, lines 1-5; page 41, lines 3-24; page 42, lines 1-24; page 43, lines 1-24; page 44, lines 1-24; page 45, lines 1-11. The claimed method differs only in the gauge of the needle used to administer the gel. However, adjustment of the viscosity for other methods of administration is taught at page 37, lines 13 -19. Therefore, those of ordinary skill would have found it well within their ability to adjust the pH according to whatever gauge needle was being used according to the teachings of Brodeck et al. The instant claims would have therefore been obvious to one of ordinary skill in the art at the time of invention given the teachings of Brodeck et al.

### ***Conclusion***

This is a continuation of applicant's earlier Application No. 10/080,502. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

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even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 4,15, 55, 64, 65, 82 and 83 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615

Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

caz